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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/739,457	12/17/2003	Hendrik-Jan Houthoff	570-29 PCT/US/CON	9335
23869	7590	07/07/2004	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICO TURNPIKE SYOSSET, NY 11791			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 07/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/739,457

Applicant(s)

HOUTHOFF ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Preliminary Amendment.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3-22-04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' Preliminary Amendment is acknowledged.
2. Claims 1-16 are pending and under consideration.

Priority Statement

3. The status of U.S. application 09/581,013 must be updated to indicate that it is now U.S. Pat. No. 6,733,983.

Specification

4. The following is a recitation of 37 C.F.R. §1.74, Reference to Drawings:

When there are drawings, there shall be a brief description of the several views of the drawings, and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures, and to the different parts by use of reference letters or numerals (preferably the latter).

The specification does not contain a section entitled, "Brief Description of Drawings".

5. The attempt to incorporate subject matter into this application by reference to W094/14069 is improper because the instant specification recites that "KP90 was prepared from starting material from crude mycobacterial mass as described in WO-A-94/14069". However, the procedures in the reference utilize different parameters of centrifugation and sonication than the instant specification, among other differences in procedure, and the reference is not directed to any preparation designated as KP90.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The instant claims are drawn to a method for identifying a *Mycobacterium* species comprising: a) contacting ≥ 1 ImCRAC component of a *Mycobacterium* species with a body fluid from a human or animal; b) contacting ≥ 1 antibody which is capable of reacting with a mycobacterial antigen, with said body fluid sample; and c) detecting the presence of Ag-Ab complexes, and identifying the *Mycobacterium* species present in said body fluid sample.

It is unclear how one detects a whole *Mycobacterium* by merely detecting Ag-Ab complexes. It is unclear how adding both the antigen and the antibody to a body sample detects whole *Mycobacterium* which may or may not be present.

9. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *M. tuberculosis* KP90 antigen preparation and antibodies produced against *M. tuberculosis*, does not reasonably provide enablement for other species of *Mycobacteria*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - The instant claims are drawn to a method and kit for identifying any/all *Mycobacterium* species comprising: a) contacting ≥ 1 ImCRAC component of any/all *Mycobacterium* species with a body fluid from a human or animal; b) contacting ≥ 1 antibody which is capable of reacting with a mycobacterial antigen of any/all *Mycobacterium* species, with said body fluid sample; and c) detecting the presence of Ag-Ab complexes, and **identifying** the *Mycobacterium* species present in said body fluid sample.

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The state of the prior art – While the prior art teaches ImCRAC and the production of antibodies capable of binding to various antigens from various species of *Mycobacterium*, there is a lack of predictability in the art that the use of any ImCRAC regardless of its origin along with any antibody which can bind to any antigen of any species of *Mycobacterium* can successfully identify other species of *Mycobacterium*.

The amount of direction/guidance/working examples present – The instant specification utilizes only a crude extract of *M. tuberculosis* and antibodies raised against *M. tuberculosis*. The instant specification provides insufficient guidance/working examples commensurate with the scope of the instant claims, i.e., identification of any/all species of *Mycobacterium* no matter of the origin of the ImCRAC or the specificity of the antibody.

Thus, due to the lack of guidance/working examples present, the instant claims constitute merely an invitation to experiment without a reasonable expectation of success.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 6,733,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of identifying *Mycobacterium* utilizing the same methods steps and reagents.

Conclusion

12. No claims are allowed.

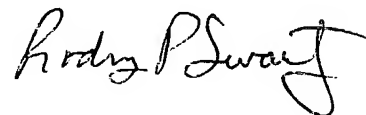
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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

June 27, 2004